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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,588	02/10/2006	Petra Lutter	14462-00006	3511

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

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11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,588	LUTTER ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *6 and 12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0106*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1–26 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, claim(s) 1-11 and 20-26 (in part), drawn to a CD4+CD25+ T cell comprising galectin-10, the species an antibody that binds galectin-10 and CD25, the species rheumatoid arthritis and the species SEQ ID NO: 1 in the reply filed on 08/26/2009 is acknowledged. The traversal is on the ground(s) that groups I and II share a common technical feature, both groups are in the same category, the groups are analogous to a plug and a socket, both groups can be searched without undue burden, the examiner's determination is subjective, Leiferman does not disclose that CLC/galectin-10 antibodies bind CD4+CD25+ T cell, the examiner's restriction of the sequences is misplaced. This is not found persuasive because unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Therefore, even if a group of inventions share the same technical feature, or are in the same category or are analogous to a plug and socket, if that technical feature, category or analogy does not make a contribution over the prior art, then unity is lacking. In the present case the documents cited in the restriction requirement and the documents cited in this Office action show that there is a lack of novelty or inventive step with respect to group I. Therefore, the inventions of groups I and II do not fulfill the requirements for unity of invention. Search burden is not germane to the determination of unity. The examiner declines to accept

applicants' characterization of Leiferman's antibodies because there is no discernable difference between the galectin-10 to which Leiferman's antibodies bind and the galectin-10 recited in claim 1. SEQ ID NO: 1 does not share a special technical feature with the other sequences because SEQ ID NO: 1 is well known in the art, as indicated in the restriction requirement and in the prior art rejections that follow.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12–19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/26/2009.

Claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/26/2009.

Drawings

Figure 8 is presented on separate panels. However, the brief description of the drawings refers only to Figure 8. If the drawings show Figures 1A, 1B, and 1C, for example, and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected. See MPEP § 601.01(g). The Brief Description of the Drawings and the rest of the specification must be amended to accordingly.

Specification

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See page 22. This list is not meant to be exhaustive. The

specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO: 23" is permissible and the fragment need not be separately presented in the "Sequence Listing."

Correction is required.

Claim Objections

Claim 7 is objected to because of the following informalities: "galectin" is misspelled. Appropriate correction is required.

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A cell containing a protein homologous to galectin-10 (claim 3) could be infringed without infringing a cell that contains galectin-10 (claim 1).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 23–26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass a "binding agent." According to the specification:

> In the widest sense, the binding agent is therefore also, in accordance with the invention, an addressed molecule which binds to a suitable signal-mediating receptor on Tregs containing galectin and generates a feedback on the basis of the galectin which is present in the Treg. (page 8, full paragraph 1).

There are no structural limitations to the binding agent. Accordingly, the genus of binding agents is highly variant. When there's a substantial variation within a genus, an applicant has to describe a sufficient number of species to reflect the variation.

The specification describes an siRNA molecule that reduces the suppressive ability of $CD4^+CD25^+$ T cells (Example 19). However, Galectin-10 specific antibodies and recombinant galectin-10 protein had no effect on cultures of $CD25^+$ Treg cells (Kubach (Blood. 2007 Sep 1;110(5):1550-8), page 1554, right column, full paragraph 1). Therefore, the described species, i.e., galectin-10 siRNA, does not reflect the variation in the genus.

A generic statement such as "binding agent" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the agents that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish

them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

The disclosure of screening assays and general classes of compounds is not adequate to describe an agent that "generates a feedback on the basis of the galectin which is present in the Treg" because it does not describe which agents have such activity.

Without a correlation between structure and function, the specification does little more than define a binding agent by function. That is not sufficient to satisfy the written description requirement because definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the genus of binding agents that "generate… a feedback on the basis of the galectin which is present in the Treg."

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7 and 8 are directed to or encompass a $CD4^{+}CD25^{+}$ T cell comprising galectin-10, wherein the galectin-10 is secreted, in the membrane or on the surface. According to Kubach (Blood. 2007 Sep 1;110(5):1550-8) single cell staining and flow cytometry showed a strictly

intracellular expression of galectin-10 in $CD25^+$ Treg cells (Abstract) and that no galectin-10 could be detected on the cell surface or in the supernatants of $CD25^+$ Treg cells. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated $CD4^+CD25^+$ T cell comprising galectin-10, wherein the galectin-10 is located in the cytosol, does not reasonably provide enablement for an isolated $CD4^+CD25^+$ T cell comprising galectin-10, wherein the galectin-10 is secreted, in the membrane or on the surface. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 7 and 8 are directed to or encompass an isolated $CD4^+CD25^+$ T cell comprising galectin-10, wherein the galectin-10 is secreted, in the membrane or on the surface. According to Kubach (Blood. 2007 Sep 1;110(5):1550-8) single cell staining and flow cytometry showed a strictly intracellular expression of galectin-10 in $CD25^+$ Treg cells (Abstract) and that no galectin-10 could be detected on the cell surface or in the supernatants of $CD25^+$ Treg cells. There are no working examples of an isolated $CD4^+CD25^+$ T cell comprising galectin-10, wherein the galectin-10 is secreted, in the membrane or on the surface. The examiner is aware working examples are not required. Lack of a working example is, however, a factor to be considered. The specification lacks guidance for isolating a $CD4^+CD25^+$ T cell comprising galectin-10, wherein the galectin-10 is secreted, in the membrane or on the surface. In view of

the breadth of the claims and the limited amount of direction and working examples provided by the inventor, it would require undue experimentation for the skilled artisan to make the full scope of the claimed invention.

Claims 24–26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising an isolated $CD4^+CD25^+$ T cell, does not reasonably provide enablement for a diagnostic agent which comprises a test system as defined in claim 20. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to or encompass a diagnostic agent, which encompasses or implies a diagnostic use. Claims 25 and 26 enumerate diagnostic uses. When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See M.P.E.P. 2164.01(c).

There are no working examples of any disease in which the presence or absence of $CD4^+CD25^+$ T cells is diagnostic. The examiner is aware working examples are not required. Lack of a working example is, however, a factor to be considered. Furthermore, the regulation of autoimmunity is complex. See, for example, Salomon (Annu Rev Immunol. 2001;19:225-52), paragraph bridging pages 226-227. To practice the invention in a manner consistent with the breadth of the claims would require a substantial inventive contribution on the part of a skilled practitioner, involving the determination of those diseases in which $CD4^+CD25^+$ T cells could be

diagnostic. It is this additional characterization that is needed in order to permit a skilled artisan to achieve a diagnostic use that constitutes undue experimentation.

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the complexity in the art, it would require undue experimentation for the skilled artisan to use the full scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 10, 20 and 23–26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it recites the term "homologous protein." Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of a "homologous protein" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim 5 is indefinite because it is unclear if the cell contains SEQ ID NO: 1, SEQ ID NO: 2, or an isoform. The metes and bounds are not clearly set forth.

Claim 10 recites the limitation "the nucleic acid sequence." There is insufficient antecedent basis for this limitation in the claim.

The term "suitable" in claim 20 is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 24–26 depend from claim 20, and thus also share this defect.

Claims 20 and 23–26 are directed to a "binding agent." According to the specification: "In the widest sense, the binding agent is therefore also, in accordance with the invention, an addressed molecule which binds to a suitable signal-mediating receptor on Tregs containing galectin and generates a feedback on the basis of the galectin which is present in the Treg (page 8, full paragraph 1). Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "generates a feedback on the basis of the galectin which is present in the Treg" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of "binding agent." The metes and bounds are not clearly set forth.

Claims 25 and 26 are indefinite over the recitation of "specifically" because it unclear whether the features introduced by such language are a) intended to limit the generic recitation of "diseases," or b) merely exemplary of "diseases."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3–5, 7–11 and 20–26 are rejected under 35 U.S.C. 102(b) as being anticipated by Jonuleit (J Exp Med. 2001 Jun 4;193(11):1285-94) or Jonuleit (J Exp Med. 2002 Jul 15;196(2):255-60) in view of Kubach (Blood. 2007 Sep 1;110(5):1550-8).

A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"
(B) Explain the meaning of a term used in the primary reference; or
(C) Show that a characteristic not disclosed in the reference is inherent.

MPEP § 2131.01.

Jonuleit (2001) discloses isolated human $CD4^+CD25^+$ T cells (page 1286, right column, full paragraph 3).

Jonuleit (2002) discloses isolated human $CD25^+$ Treg cells that were isolated as described by Jonuleit (2001) (page 256, right column, full paragraph 2).

Kubach discloses human $CD25^+$ Treg cells that were isolated as described by Jonuleit (2002) (paragraph bridging pages 1550-1551). CD25+ Treg cells constitutively express galectin-10 (Abstract).

Therefore, Jonuleit (2001) or Jonuleit (2002) discloses an isolated regulatory $CD4^+CD25^+$ T cell which comprises at least one galectin-10 as target or marker.

Jonuleit's (2001) or Jonuleit's (2002) $CD4^+CD25^+$ cells contain human galectin-10 because they are human cells.

Claim 3 is indefinite because it recites the term "homologous protein," as discussed above. Jonuleit's (2001) or Jonuleit's (2002) $CD4^+CD25^+$ cells contain a homologous protein in the absence of evidence to the contrary.

Jonuleit's (2001) or Jonuleit's (2002) cells are consistent with those claimed. Since the Office does not have the facilities for examining and comparing the claimed cells with Jonuleit's (2001) or Jonuleit's (2002) cells, the burden is on applicant to show a novel or unobvious difference between the claimed cells and the cells of the prior art (i.e., that the cells of the prior art do not possess SEQ ID NO: 1 or an isoform of SEQ ID NO: 1, that the cells of the prior art are not characterized in that at least one nucleic acid encoding at least one galectin is present, optionally, comprises one or more noncoding sequences, a poly(A) sequence, recognition sequences or regulatory sequences, and the cells of the prior art do not possess SEQ ID NO: 6). It is further noted that Kubach reports that 3 isoforms of galectin-10 are constitutively expressed by human $CD25^+$ Treg cells (page 1550, right column, first paragraph), and that all isoforms were detected (paragraph bridging pages 1552-1553).

Kubach also teaches that single cell staining and flow cytometry showed a strictly intracellular expression of galectin-10 in $CD25^+$ Treg cells (Abstract) and that no galectin-10 could be detected on the cell surface or in the supernatants of $CD25^+$ Treg cells.

Jonuleit (2001) (page 1287, left column, full paragraph 2) and Jonuleit (2002) (page 256, left column, full paragraph 3) also disclose a test system comprising IL-2, i.e., "at least one binding agent," at least one $CD4^+CD25^+$ T cell and a multi-well plate, i.e., a pharmaceutically acceptable support.

Jonuleit (2001) discloses a test system comprising $CD4^+CD25^+$ T cells and DCs, PBMCs or T cells, and IL-2, IL-4, PHA, anti-CD-3 or anti-CD28, i.e., a further test substance which can elicit an immune response (page 1286, right column, penultimate paragraph through page 1287, left column, full paragraph 4; paragraph bridging pages 1288-189).

Jonuleit (2002) discloses a test system comprising $CD4^+CD25^+$ T cells and DCs or T cells, and IL-2, anti-CD3 or anti-CD28, i.e., a further test substance which can elicit an immune response (page 256, left column, full paragraph 3 through page 256, paragraph bridging left and right columns).

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Stassen (Eur J Immunol. 2004 May;34(5):1303-11) in view of Kubach (Blood. 2007 Sep 1;110(5):1550-8).

A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"
(B) Explain the meaning of a term used in the primary reference; or
(C) Show that a characteristic not disclosed in the reference is inherent.

MPEP § 2131.01.

Stassen discloses an isolated regulatory $CD4^+CD25^+$ T cell, which consists of the $CD4^+CD25^+\beta7^+$ subpopulation (page 1309, left column, last full paragraph). Kubach discloses that CD25+ Treg cells constitutively express galectin-10 (Abstract). Therefore, Stassen discloses an isolated regulatory $CD4^+CD25^+$ T cell which comprises at least one galectin-10 as target or marker, which consists of the $CD4^+CD25^+\beta7^+$ subpopulation.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration under 37

CFR 1.131. Alternatively, the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 CFR 1.132 establishing that the article is describing applicant's own work. An affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference under 35 U.S.C. 102(a). In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). See M.P.E.P. 715.01(c)I.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonuleit (J Exp Med. 2001 Jun 4;193(11):1285-94) or Jonuleit (J Exp Med. 2002 Jul 15;196(2):255-60) in view of Kubach (Blood. 2007 Sep 1;110(5):1550-8) as applied to claim 1 above, and further in view of GenBank Accession No. L01664.

Jonuleit (2001) or Jonuleit (2002) in view of Kubach teach an isolated regulatory $CD4^+CD25^+$ T cell which comprises galectin-10, as discussed above. Jonuleit (2001) or Jonuleit (2002) in view of Kubach do not explicitly teach the amino acid sequence of SEQ ID NO: 1 or its encoding nucleic acid sequence SEQ ID NO: 6. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to isolate these cells from humans because one of ordinary skill in the art would be motivated to study these cells. See, for example, Jonuleit (2001), page 1293, left column, full paragraph 1. Furthermore, SEQ ID NO: 1

and SEQ ID NO: 6 are well known in the art. See, for example, GenBank Accession No. L01664. The GenBank nucleic acid sequence comprises SEQ ID NO: 6, its associated amino acid sequence comprises SEQ ID NO: 1, as indicated in the sequence comparisons below:

```
 Query Match           100.0%;  Score 598;  DB 13;  Length 598;
 Best Local Similarity   100.0%;
 Matches  598;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 CAATTCAGAAGAGCCACCCAGAAGGAGACAACAATGTCCCTGCTACCCGTGCCATACACA 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 CAATTCAGAAGAGCCACCCAGAAGGAGACAACAATGTCCCTGCTACCCGTGCCATACACA 60

Qy         61 GAGGCTGCCTCTTTGTCTACTGGTTCTACTGTGACAATCAAAGGGCGACCACTTGTCTGT 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GAGGCTGCCTCTTTGTCTACTGGTTCTACTGTGACAATCAAAGGGCGACCACTTGTCTGT 120

Qy        121 TTCTTGAATGAACCATATCTGCAGGTGGATTTCCACACTGAGATGAAGGAGGAATCAGAC 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TTCTTGAATGAACCATATCTGCAGGTGGATTTCCACACTGAGATGAAGGAGGAATCAGAC 180

Qy        181 ATTGTCTTCCATTTCCAAGTGTGCTTTGGTCGTCGTGTGGTCATGAACAGCCGTGAGTAT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 ATTGTCTTCCATTTCCAAGTGTGCTTTGGTCGTCGTGTGGTCATGAACAGCCGTGAGTAT 240

Qy        241 GGGGCCTGGAAGCAGCAGGTGGAATCCAAGAACATGCCCTTTCAGGATGGCCAAGAATTT 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 GGGGCCTGGAAGCAGCAGGTGGAATCCAAGAACATGCCCTTTCAGGATGGCCAAGAATTT 300

Qy        301 GAACTGAGCATCTCAGTGCTGCCAGATAAGTACCAGGTAATGGTCAATGGCCAATCCTCT 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 GAACTGAGCATCTCAGTGCTGCCAGATAAGTACCAGGTAATGGTCAATGGCCAATCCTCT 360

Qy        361 TACACCTTTGACCATAGAATCAAGCCTGAGGCTGTGAAGATGGTGCAAGTGTGGAGAGAT 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 TACACCTTTGACCATAGAATCAAGCCTGAGGCTGTGAAGATGGTGCAAGTGTGGAGAGAT 420

Qy        421 ATCTCCCTGACCAAATTTAATGTCAGCTATTTAAAGAGATAACCAGACTTCATGTTGCCA 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 ATCTCCCTGACCAAATTTAATGTCAGCTATTTAAAGAGATAACCAGACTTCATGTTGCCA 480

Qy        481 AGGAATCCCTGTCTCTACGTGAACTTGGGATTCCAAAGCCAGCTAACAGCATGATCTTTT 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 AGGAATCCCTGTCTCTACGTGAACTTGGGATTCCAAAGCCAGCTAACAGCATGATCTTTT 540

Qy        541 CTCACTTCAATCCTTACTCCTGCTCATTAAAACTTAATCAAACTTCAAAAAAAAAAAA 598
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 CTCACTTCAATCCTTACTCCTGCTCATTAAAACTTAATCAAACTTCAAAAAAAAAAAA 598


 Query Match           100.0%;  Score 738;  DB 2;  Length 142;
 Best Local Similarity   100.0%;
 Matches  141;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;
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Qy          1 SLLPVPYTEAASLSTGSTVTIKGRPLVCFLNEPYLQVDFHTEMKEESDIVFHFQVCFGRR 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          2 SLLPVPYTEAASLSTGSTVTIKGRPLVCFLNEPYLQVDFHTEMKEESDIVFHFQVCFGRR 61

Qy         61 VVMNSREYGAWKQQVESKNMPFQDGQEFELSISVLPDKYQVMVNGQSSYTFDHRIKPEAV 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         62 VVMNSREYGAWKQQVESKNMPFQDGQEFELSISVLPDKYQVMVNGQSSYTFDHRIKPEAV 121

Qy        121 KMVQVWRDISLTKFNVSYLKR 141
              |||||||||||||||||||||
Db        122 KMVQVWRDISLTKFNVSYLKR 142.
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Furthermore, Kubach reports that 3 isoforms of galectin-10 are constitutively expressed by human $CD25^+$ Treg cells (page 1550, right column, first paragraph), and that all isoforms were detected (paragraph bridging pages 1552-1553). Kubach is cited to show the characteristics or properties of the prior art CD25+ Treg cells. Therefore, Kubach need not be available as prior art before applicant's filing date. See M.P.E.P. 2124.

Therefore, the isolation of $CD4^+CD25^+$ T cells comprising the amino acid sequence of SEQ ID NO: 1 and the nucleic acid sequence of SEQ ID NO: 2 would naturally flow from following the teachings of the prior art.

The invention is prima facie obvious over the prior art.

Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lehmann (Proc Natl Acad Sci U S A. 2002 Oct 1;99(20):13031-6) discloses that the integrin $\alpha_E\beta_7$ identifies the most potent subpopulation of regulatory $CD25^+$ murine T cells (Abstract). However, Rosenberg (Blood. 2007 Sep 1;110(5):1407-8) teaches that there is no evidence for a gene or genes encoding galectin-10/CLC in the mouse genome.

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DSR
NOVEMBER 20, 2009